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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/634,655 | 08/05/2003 | Randall Lashinski | MITRAL.001CP3 | 6367 |

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| EXAMINER | |
|---|---|
| CHATTOPADHYAY, URMI | |
| **ART UNIT** | **PAPER NUMBER** |
| 3738 | |

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/634,655 | LASHINSKI ET AL. | |
| | Examiner | Art Unit | |
| | Urmi Chattopadhyay | 3738 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-6 and 8-47* is/are pending in the application.

4a) Of the above claim(s) *24-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,8-23,46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/21/05, 2/22/05, 4/11/05*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

1. The amendment filed 4/11/05 has been entered. The changes to the specification and claims have been approved by the examiner. Claims 2 and 7 have been canceled, and new claims 46 and 47 have been added. Claims 1, 3-6 and 8-47 are pending, of which claims 24-45 remain withdrawn from consideration. The claims being considered for further examination on the merits are claims 1, 3-6, 8-23, 46 and 47.

### *Information Disclosure Statement*

2. The information disclosure statements filed on 2/21/05, 2/22/05 and 4/11/05 have been considered. The IDSs filed 2/21/05 and 2/22/05 are identical to each other.

### *Claim Objections*

3. Claim 3 is objected to because of the following informalities: the claim is dependent on claim 2, which has been canceled. It appears that the claim should be dependent on claim 1, and will so be interpreted for examination purposes. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 47 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 47 is indefinite because it is unclear if applicant is attempting to claim the deployment catheter with the implant as a combination claim. Claim 13, on which claim 47 depends, does not structurally claim the deployment catheter as a part of the claimed invention of an implant. Therefore, further limiting the deployment catheter in claim 47 does not further limit the claimed invention. For examination purposes, the deployment catheter is not being considered a claimed element of the invention.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 3, 5, 6, 8, 9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vidlund et al. (USPAP 2003/0130731 A1, as cited in previous office action) in view of Adams et al. (USPAP 2003/0083538 A1, as cited in previous office action).

Vidlund et al. discloses a medical device for remodeling a mitral valve annulus adjacent to the coronary sinus with all the elements of claim 1, but is silent to the central segment being concave in a second direction. See Figures 4h-4i and [0124]-[0125] for an elongate body (110h) having proximal and distal ends. The elongate body (110h) is movable from a first, flexible

configuration (Figure 4h) for transluminal delivery to at least a portion of the coronary sinus to a second configuration (Figure 4i) for remodeling the mitral valve annulus. A forming element (90) is attached to the elongate body (110h) for manipulating the elongate body (110h) from the first delivery configuration to the second remodeling configuration. See [0124] for the elongated body (110h) having a final shape with an increased radius of curvature in some regions and a decreased radius of curvature in other regions. Adams et al. teaches a device (50) having a "w" configuration implanted into the coronary sinus, wherein a force is applied to a discrete portion (23) of the atrial wall (21) of the coronary sinus (14) in order to reshape the mitral valve annulus for treating dilated cardiomyopathy. See Figure 3 and [0051]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Adams et al. to modify the device of Vidlund et al. such that the final shape of the device is of a "w". The "w" configuration includes proximal and distal segments that are concave in a first direction and central segment that is concave in a second direction. This shape will apply a force to a discrete portion of the atrial wall of the coronary sinus to reshape the mitral valve annulus in treating dilated cardiomyopathy. Because the central segment will be concave in a direction opposite to the concave direction shown in Figure 4i in the remodeling configuration, the forming element (90) will extend outside the body (110h) by being exposed between the wedge-shaped segments (95) that make up the body along the central segment.

Claim 3, see Figures 4h-4i and [0124] for the body comprising several wedge-shaped segments (95) with holes therethrough, together forming a tube with a plurality of transverse slots therein.

Claims 5 and 6, see [0124] for the apparatus being movable from the delivery configuration to the remodeling configuration in response to movement of the forming element (90).

Claim 8, see [0124] for an anchor assembly for engaging a site within a vessel.

With respect to claim 9, Vidlund et al. does not expressly disclose the embodiment shown in Figures 4h-4i including an anchor in the form of a barb for piercing the wall of the vessel, as required by claim 9. Vidlund et al. does, however, disclose a body (110c) including barbs in the embodiment shown in Figure 4c in order to engage with the vessel wall for maintaining the position of the body (110c) within the vessel. See Figure 4c and [0119]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention make the distal anchor assembly of the embodiment shown in Figures 4h-4i in the form of a barb in order to pierce the vessel wall to maintain the position of the body (110h) within the vessel.

With respect to claims 11 and 12, Vidlund et al. does not expressly disclose that the apparatus has an axial length of no more than about 10 cm and a maximum cross sectional dimension of no more than about 10 mm, as required by claims 11 and 12, respectively. However, it appears in [0125] that the apparatus of Vidlund et al. is sized and shaped for implantation in the coronary sinus of the heart, which is the same location the apparatus of applicant's invention is being implanted. Given the dimensions of a human coronary sinus, it is obvious that the apparatus of Vidlund et al. would meet the axial length and maximum cross sectional dimension requirements of claims 11 and 12 in order for it to fit and operate within the coronary sinus.

8. Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vidlund et al. and Adams et al. as applied to claims 1 and 8 above, and further in view of Alferness et al. (USPAP 2003/0105520 A1, as cited in previous office action).

Vidlund et al., as modified by Adams et al., discloses a medical device for remodeling a mitral valve annulus adjacent to the coronary sinus with all the elements of claim 1, but is silent to the apparatus further comprising a lock for retaining the body in the second configuration, as required by claim 4. See [0124] for the forming element (90) being attached to an anchor assembly provided on the distal end of body (110h). Alferness et al. teaches a device (30) implanted in the coronary sinus, wherein a lock (44) on a distal anchor (36) locks the distal anchor (36) to a cable (42) in order to be able to adjust the amount of tension in the cable (42) to achieve a device configuration that provides the desired mitral valve geometry. See Figure 5 and [0021], [0035] and [0036]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Alferness et al. to modify the apparatus of Vidlund et al. by further including a lock on the anchor assembly for locking the forming element (90) to the anchor assembly in order to adjust and maintain the body (110h) in the second configuration.

Vidlund et al. and Adams et al. are also silent to the apparatus further comprising a first tissue anchor at the proximal end of the body, as required by claim 10. See [0124] for a second tissue anchor assembly at the distal end of the body (110h). Alferness et al. teaches the device (30) including a proximal anchor (36) and a distal anchor (32) in order to fix the device within the coronary sinus so that the configuration of the device can be changed to effect mitral valve geometry. See [0014] and Figure 3. It would have been obvious to one of ordinary skill in the

art at the time of applicant's invention to look to the teachings of Alferness et al. to modify the apparatus of Vidlund et al. by including a first tissue anchor at the proximal end of the body (110h) in order to fix the body (110h) within the coronary sinus so that the configuration of the body (110h) can be changed to effect mitral valve geometry.

9. Claims 13-23, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vidlund et al. in view of Adams et al. and Webster, Jr. (USPN 6,123,699, as cited in previous PTO-892) and Alferness et al. (USPAP 2002/0169504 A1, as cited in previous office action).

Vidlund et al. discloses a medical device for remodeling a mitral valve annulus adjacent to the coronary sinus with all the elements of claim 13, but is silent to manipulation of the forming element deflecting the central section laterally with respect to at least a portion of the proximal and distal sections. See rejection of claim 1, supra. Adams et al. teaches a device (50) with a laterally deflected central section (56) that is implanted into the coronary sinus, wherein a force is applied to a discrete portion (23) of the atrial wall (21) of the coronary sinus (14) in order to reshape the mitral valve annulus for treating dilated cardiomyopathy. See Figure 3 and [0051]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Adams et al. to modify the device of Vidlund et al. such that the final shape of the device includes a central segment that is laterally deflected. Webster, Jr. teaches a steerable catheter wherein four puller wires (31) are anchored at three or four different locations along the length of the distal tip of the catheter in order to provide each quadrant with a distinct curvature. See column 7, lines 47-52. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Webster, Jr. to

modify the implant of Vidlund et al. by having the forming element (90) attached to the central segment in order for the forming element (90) to provide that section with a curvature. Manipulation of the forming element (90) will laterally deflect the central section with respect to the proximal and distal sections in achieving the configuration taught by Adams et al. in order to selectively apply a compressive force to a discrete portion of the atrial wall of the coronary sinus to reshape the mitral valve annulus in treating dilated cardiomyopathy.

Vidlund et al. is also silent to a detachable coupling on the body for removably attaching the body to a deployment catheter, as further required by claim 13. See [0125] for the body (110h) being implanted using a catheter. Alferness et al. teaches a mitral valve therapy device (30) that has a detachable coupling (46) on the proximal portion (44) of the device in order to removably attach with an introducer (56) that is used for positioning the device (30) in the coronary sinus. See [0050], [0054] and Figures 2 and 3. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings Alferness et al. to modify the implant of Vidlund et al. by including a detachable coupling on the body (110h) in order to removably attach with an introducer in the form of a catheter. The forming element (90) will extend through a lumen of the catheter and the catheter will be used to position the body (110h) in the coronary sinus.

Claim 14, see Figures 4h-4i and [0124] for the body comprising several wedge-shaped segments (95) with holes therethrough, together forming a tubular wall.

Claim 15, see Figure 4h for a substantially non-compressible first side.

Claims 16 and 17, see Figure 4h for a plurality of voids along the second side in the form of slots extending transverse to the longitudinal axis and permitting axial shortening on the second side (Figure 4i).

Claims 18 and 19, see Figure 4h for required number of slots.

Claims 20 and 21, see [0124] for the forming element (90) being an axially movable pull wire.

With respect to claim 46, Alferness et al. teaches the detachable coupling (46) as being in the form of a pin and disposed on the proximal section of the flexible body, while the catheter includes a corresponding detachable coupling in the form of a detented slot (62) for receiving and rotating around the pin to releasably lock the catheter to the device. See [0054] and Figure 3. When the detachable coupling of Alferness et al. is applied to Vidlund et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the proximal section of the flexible body include the detachable coupling in the form of a detented slot and the corresponding detachable coupling of the catheter include the pin since it has been held that mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167. The detented slot is a coupling that is capable of being rotated, specifically around the pin prior to implantation, as required by claim 46.

Claim 47 is does not further limit the claimed invention. See 112, second paragraph rejection, supra.

***Response to Arguments***

10. Applicant's arguments filed 4/11/05 have been fully considered but they are not persuasive.

11. Applicant argues that the actuation mechanism (90) of Vidlund et al. is pulled proximally for causing the frame member (110h) to change its shape for creating a single continuous curve, as shown in Figure 4i. The examiner would like to specifically point out the end of paragraph [0124], which states that the "desired final shape of the frame member 110h may reduce or enlarge a radius of curvature of the valve annulus, or a combination of both, i.e., increasing the curvature in some regions and decreasing the curvature in other regions." This clearly indicates that the final shape of the frame member (110h) does not have to have a single continuous curve.

12. In response to applicant's argument that Adams et al. teaches the use of friction fit or shape memory materials to achieve the curved configuration after delivery, and that Adams et al. provides no teaching or suggestion regarding how to use a forming element to transform the device from a delivery configuration to a remodeling configuration, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Adams et al. is used as a secondary reference, only to teach what the final shape of the frame member (110h) should be.

13. Applicant also argues that neither Vidlund et al. nor Adams et al. teaches or suggests a forming element that extends outside the body along the central segment while in the remodeling

configuration, and that in contrast, Figure 4i of Vidlund et al. illustrates a forming element that is contained entirely within the body while the device is in the remodeling configuration. As explained above, Figure 4i of Vidlund et al. is not reflective of the final shape of the body when modified by Adams et al. The central segment of the body of Vidlund et al., when the body is in a "w" remodeling configuration, will indeed have the forming element extend outside the body along the central segment by being exposed between the wedge-shaped segments (95).

14. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Motivation to combine the Adams et al. reference to the Vidlund et al. reference is provided by the Adams et al. reference, and that is to reshape the mitral valve annulus for treating dilated cardiomyopathy. Also, motivation to combine the Alferness et al. reference to the Vidlund et al. reference is provided by the Alferness et al. reference, and that is to removably attach the device with an introducer (56) that is used for positioning the device (30) in the coronary sinus. It is not impermissible hindsight to combine the references because the motivation to combine them is provided in the references themselves.

15. Applicant's arguments with respect to *amended* claim 13 have been considered but are moot in view of the new ground(s) of rejection.

*Conclusion*

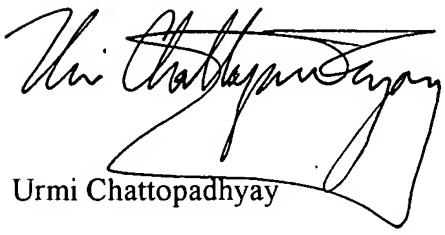
16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.

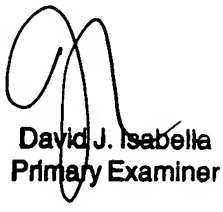
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

Art Unit 3738



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